-- PATENT APPLICATION --
-- Attorney Docket No. 25,835.11 --

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13 1/2

Applicants: M. L. Collins, et al.

Serial No.: 08/238,080

Filing Date: May 3, 1994

Title: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS

Art Unit: 1807

Examiner: Dianne Rees

CERTIFICATE OF MAILING & FACSIMILE RESPONSE

I hereby certify that this correspondence is being sent via facsimile to: Dianne Rees, at facsimile number (703) 305-7401, and is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date shown below.

LESLIE B. HENSON
(Printed Name)

Leslie B. Henson
(Signature)

APRIL 17, 1997
(Date of Deposit)

TRANSMITTAL OF ART REFERENCES

The Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Two recently published art references are attached for the Examiner's consideration. These are "Sequence Capture-PCR Improves Detection of Mycobacterial DNA in Clinical Specimens by Magiapan, et al., J. Clin. Microbiol. 34:1209-1215 (1996) and Relevance of Nucleic Acid Amplification Techniques for Diagnosis of Respiratory Tract Infections in the Clinical Laboratory by leven, et al., Clinical Microbiology Reviews, 10(2), 242-256 (1997). The reference by Magiapan is an original paper. The reference by leven is a review article which cites the Magiapan article at page 248.

Magiapan purports to report a new method for rapid identification of mycobacterial DNA in clinical samples by PCR for diagnosis of tuberculosis infections with enhanced sensitivity. Significantly, this procedure, submitted for publication in late 1995, is the same method claimed in Applicants' pending claim 25. Magiapan reports numerous difficulties encountered by those in the art in their attempts to obtain rapid identification of mycobacterial DNA in

clinical samples by PCR. Magiapan discloses a "new PCR-based strategy, sequence-capture PCR" to overcome these difficulties (page 1213; see also page 1209). Magiapan reports many advantages resulting from this new method including sensitivity enhancements of 10 to 100 fold over other methods wherein total DNA is extracted prior to amplification, elimination of potential inhibitory substances present in crude samples, and the ability to detect mycobacterial DNA in a majority of culture-negative pleural fluid samples from patients with tuberculosis (See the Discussion at pages 1213-1214). Magiapan's "new" method is illustrated in Fig. 1. It comprises the steps of contacting the sample with a support which binds with the target, separating the support and bound target polynucleotide from the sample and amplifying the target polynucleotide. This is precisely the method claimed in Applicants' claim 25.

Ieven is a review article examining the "Relevance of Nucleic Acid Amplification Techniques" for clinical diagnosis of respiratory tract infections. Ieven discusses Magiapan's method as potentially a significant advance with a number of benefits. There is no suggestion in Ieven that this method is old or obvious in light of the prior art. To the contrary, Ieven discusses the numerous difficulties encountered in the use of PCR in clinical diagnostics and describes the sequence capture method of Magiapan (i.e., Applicants' claimed method) favorably and as a recent development. Applicants submit that the Magiapan and Ieven references provide compelling contemporary evidence of the significance and unobviousness of Applicants' invention.

Respectfully submitted,
AMOCO CORPORATION

By: Norval B. Galloway
Norval B. Galloway
Attorney for Applicant
Registration No. 33,595

Date: 4/17/97

AMOCO CORPORATION
Law Department
3100 Woodcreek Drive
Downers Grove, Illinois 60515-5400
Phone: (630) 271-7417
Facsimile: (630) 271-7054

A:\2583511.AAF